February 14, 2022

Veru Reports that Independent Data Monitoring Committee for the Phase 3 Sabizabulin COVID-19 Clinical Study Recommends Continuing Study as Planned

--Planned Conditional Statistical Power Analysis was Conducted—

--Primary Efficacy Study Endpoint Is Proportion of Patients that Die on Study Up to Day 60--

--Global Phase 3 Sabizabulin COVID-19 Clinical Study for Treatment of Hospitalized Moderate to Severe COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome on Track and Clinical Results Expected 1H 2022--

MIAMI, Feb. 14, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU) today announced that the Independent Data Monitoring Committee (IDMC) has conducted a planned conditional power analysis of the first 75 randomized patients in the Global Phase 3 COVID-19 registration study evaluating novel oral sabizabulin in hospitalized patients with moderate to severe COVID-19 infection who are at high risk for acute respiratory distress syndrome (ARDS) and death and has concluded the clinical study should continue as originally designed. The IDMC performed this planned conditional statistical power analysis and review of safety of the first 75 study patients to reach the primary endpoint. Current full study recruitment is on track to yield clinical results in the first half of calendar year 2022.

The Phase 3 COVID-19 clinical study is a double-blind, multicenter, multinational, randomized (2:1), placebo-controlled study evaluating daily oral 9 mg sabizabulin for up to 21 days versus placebo in 300 hospitalized patients who have moderate to severe infection and who are at high risk for ARDS. Subjects will also be allowed to receive standard of care. The primary efficacy endpoint will be the proportion of patients that die on study up to Day 60. Secondary endpoints will include the proportion of patients without respiratory failure, days in ICU, WHO Ordinal Scale for Clinical Improvement change from baseline, days on mechanical ventilation, days in the hospital, and viral load.

In January 2022, the Phase 3 COVID-19 program received Fast Track designation by FDA. Fast Track designation aims to expedite the development and review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to fill unmet medical needs. Filling an unmet medical need is defined as providing a therapy where

none exists or providing a therapy which may be potentially better than available therapy.

The Phase 3 COVID-19 study is being conducted in the United States, Brazil, Argentina, Mexico, Colombia and Bulgaria and is on track. Clinical results are expected in the first half of calendar year 2022.

“This conditional power analysis reviewed the clinical efficacy data from the first 75 patients to make a determination whether the study should be stopped for lack of efficacy, or continue as planned as the current study design and sample size are appropriate,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “We are pleased that the Independent Data Monitoring Committee has confirmed that based on this conditional statistical power analysis we should continue the study as planned. The Phase 3 COVID-19 clinical study is on track to have clinical results the first half of this year.”

Dr. Steiner further noted: “COVID-19 global cases are at exceedingly high levels. In fact, the Omicron variant has driven the US death toll higher than at any point during the Fall of 2021’s Delta variant peak. It is clear that an effective and safe oral therapeutic that prevents deaths in hospitalized patients with moderate to severe COVID-19 disease who are at high risk for ARDS is desperately needed. FDA has confirmed by granting Fast Track that an effective therapy for hospitalized patients with COVID-19 remains an unmet medical need. We strongly believe that sabizabulin with its anti-viral and anti-inflammatory properties and a favorable safety profile may be that greatly needed oral therapy for these hospitalized COVID-19 patients at risk for ARDS.”

About Sabizabulin for COVID-19
Microtubule trafficking is critical for viruses to be transported, replicated, assembled, and released from the cell. Microtubules also play a role in the inflammatory process including the cytokine release syndrome (cytokine storm). Sabizabulin is a cytoskeleton disruptor which blocks microtubule trafficking and has the potential to treat both the SARS-CoV-2 viral infection and the cytokine storm and septic shock that leads to ARDS and the high COVID-19 mortality rates.

About Veru Inc.
Veru is an oncology biopharmaceutical company with a principal focus on developing novel medicines for the management of breast and prostate cancers.

The Company’s late-stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist, and sabizabulin, a cytoskeleton disruptor.

Current studies on the two drugs include:

- Enrolling Phase 3 ARTEST study of enobosarm in androgen receptor positive, estrogen receptor positive, and human epidermal growth factor receptor two negative (AR+ ER+ HER2-) metastatic breast cancer with AR ≥ 40% expression (third-line metastatic setting), and which has been granted Fast Track designation by the FDA.

- Planned Q1 2022 Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) combination in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% expression (second-line metastatic setting). The Company has entered into a clinical study collaboration and supply agreement with Lilly regarding Lilly’s supply of

Verzenio® (abemaciclib) for the ENABLAR-2 study.

- Planned Q1 2022 Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% expression (third-line metastatic setting).

The Company has determined that patients who have ≥ 40% androgen receptor nuclei staining by immunohistochemistry in their breast cancer tissue, a measure of AR expression, are most likely to respond to enobosarm. Consequently, Veru is developing a companion diagnostic to determine a patient's androgen receptor expression status, and has partnered with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostics, which will develop and, if it is approved, commercialize the companion AR diagnostic.

Veru's late-stage prostate cancer portfolio comprises sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

Current studies on these drugs include:

- Enrolling Phase 3 VERACITY in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy.

- Enrolling Phase 2 dose-finding study of VERU-100 in advanced hormone-sensitive prostate cancer.

- Planned Phase 2b study of zuclomiphene citrate in men with advanced prostate cancer undergoing androgen deprivation therapy who suffer from hot flashes.

In addition, sabizabulin, which has dual antiviral and anti-inflammatory effects, is currently enrolling in a Phase 3 COVID-19 study for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome, and which has been granted Fast Track designation by the FDA.

Veru also has a commercial sexual health division - Urev, the proceeds of which help fund its drug development programs, comprised of 2 FDA approved products:

- ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, commercialization launch plans are underway.

- FC2 Female Condom® (internal condom), for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections which is sold in the U.S. and globally.

Forward-Looking Statements
The statements in this release that are not historical facts are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements regarding whether current and future clinical development and results, including whether sabizabulin will be an effective therapy for hospitalized COVID-19 patients, will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates and companion diagnostic; whether the drug candidates will be approved for the targeted line of therapy; the anticipated design and scope for clinical studies and FDA acceptance of such design and

scope, whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are or continue to be available; whether the expected commencement and timing of the Company's clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic will be met, including the Phase 3 VERU-100 clinical study and the sabizabulin clinical study for the treatment of hospitalized Covid-19 patients at high risk of ARDS; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need or, what dosage, if any, might be approved for use in the US or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, and the timing of the Company's submissions to FDA and FDA's review of all such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; when commercial launch of ENTADFI will occur and the Company's ability to develop its own direct to patient telemedicine and telepharmacy services platform to market and distribute ENTADFI; the magnitude of any potential revenues generated by ENTADFI; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; that demand for the FC2 in the US prescription business and the Company's commercial products, including FC2 and ENTADFI, will continue and further financially support the Company's clinical oncology development pipeline; and whether and when the Company will launch its own telemedicine and internet pharmacy services platforms to market either FC2 or ENTADFI and whether either such platform will increase awareness or drive sales of such products. These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the development of the Company's product portfolio and the results of clinical studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development; the timing of any submission to the FDA and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company's existing products and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical studies, supply chain and other third-party providers, commercial efforts, and business development operations; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement

changes; the Company's ability to successfully commercialize any of its products, if approved; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, and development costs; the Company's ability to protect and enforce its intellectual property; the potential that delays in orders or shipments under government tenders or the Company's U.S. prescription business could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; the concentration of accounts receivable with our largest customers and the collection of those receivables; the Company's production capacity, efficiency and supply constraints and interruptions, including potential disruption of production at the Company's and third party manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's and third party facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; costs and other effects of litigation, including product liability claims; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed from time to time in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the fiscal year ended September 30, 2021 and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors. The Company disclaims any intent or obligation to update these forward-looking statements.

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